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10/572,588	03/20/2006	Yuzuru Ishibashi	0152-0727PUS1	2926

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EXAMINER
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MELLON, DAVID C

ART UNIT	PAPER NUMBER
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1777

NOTIFICATION DATE	DELIVERY MODE
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01/19/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,588	<b>Applicant(s)</b> ISHIBASHI, YUZURU	
	<b>Examiner</b> DAVID C. MELLON	<b>Art Unit</b> 1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's continued traversal of the Restriction Requirement issued 3/11/2009 is noted. The Restriction Requirement was made FINAL on 5/5/2009. Applicant's continued traversal is not convincing. Applicant is noted that unity of invention is broken by PCT Rule 13.2. Applicant has provided no evidence that the process claims as such are in fact specially adapted to provide only the product as claimed. In fact, it is noted that Applicants process claims are deficient as to any manner/step towards providing the claimed varied membrane occupying ratio bundle. It is further noted that Applicant's restriction arguments (which were not timely presented) were addressed in section 13 of the previous office action.

2. The response filed on November 5, 2010 contained mention of a "contingent Petition under 37 CFR 1.181 and 1.144." Applicant is advised that 37 CFR 1.4(c) requires each distinct subject or inquiry be contained in a separate paper, since different matters may be considered by different branches or sections of the USPTO. In the present application, the "contingent Petition" would be considered by a different section of the USPTO. Accordingly, the Applicant must submit the petition as a separate paper, if the Applicant desires to seek Director review of the requirement.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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**4. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Regarding claims 11-12, the recitation of “normally set to” renders the claim indefinite. The recitation implies that there are alternative occupying rate settings that are possible in the claimed device. This renders the claims metes and bounds with respect to occupying rate indefinite because it is unknown what all the occupying rates could be.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**8. Claims 1-2 and 11-12 are rejected under 35 U.S.C. 103(a) as obvious over Haworth et al. (USP Re. 36,125).**

Regarding claims 1, 2, and 11-12, Haworth et al. discloses a hollow fiber bundle wound on a core for radially outward flow of a fluid (Abstract) in figure 1 comprising:

A membrane occupying rate set to between 0.3-0.6 (C1/L60-C2/L12 - “where the packing fraction approaches the value of about 60%”)

- A hollow fiber membrane bundle formed of a plurality of hollow fiber membranes (70) (the bundle can also be considered rod shaped)
- A housing (12)
- An inlet (26) and an outlet (41, 40), additionally, gas inlet (22) and gas outlet (24)

Furthermore, Haworth et al. discloses a mass transfer device including a hollow fiber bundle wound on a core for radially outward flow (Abstract) wherein the packing fraction of the hollow fibers increases radially outward (C3/L25-43). Additionally, Haworth et al. discloses using incremental packing (C3/L40-53). Furthermore, Haworth et al. discloses that the range of packing fractions be such that the inner fraction is 60-95% of that of the outer packing fraction (C3/L10-27).

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- Part A has a cross sectional area extending symmetrically from a line bisecting the nozzle (form a line through the housing and from the center of the housing there is a symmetrical distribution); where this extends a substantial distance or also considered to approximately extend to the center

The membrane occupying rate decreases along the coincident line from the nozzle to the opposite side (it decreases and then increases again - the claims do not require it to remain decreased nor do the claims preclude a subsequent increase).

With respect to  $\frac{1}{4}$  or more of the cross-sectional area of the bundle, it is asserted that this limitation is met inherently. Further, no cross-sectional area has been specifically defined by Applicant. Thus, a side cross sectional area may be considered based upon a longitudinal slice.

With respect specifically to neighboring versus non-neighboring, Applicant has not at this point defined such terms in a manner to preclude application of annular ring or gradient type structures.

**9. Claims 1-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boivin et al. (US 2002/0079260) and further in view of Haworth et al. (USP Re. 36,125).**

Regarding claims 1-2 and 11-12, Boivin et al. discloses a hollow fiber membrane (abstract) in figures 1 and 5 comprising:

- A hollow fiber membrane bundle formed of a plurality of hollow fiber membranes (1) (the bundle can also be considered rod shaped)

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- A housing (2)
- An inlet (6) and an outlet (12 and 5)
- In figure 5 a membrane occupancy ratio wherein the region nearer to the inlet ports is disclosed as denser and the region away from the inlet ports is shown as less dense (see also [0023] for instance).
- The bundle of fibers has a coincident cross sectional area with that of the cylindrical housing
- Part A has a cross sectional area extending symmetrically from a line bisecting the nozzle (form a line through the housing and from the center of the housing there is a symmetrical distribution); where this extends a substantial distance or also considered to approximately extend to the center

The membrane occupying rate decreases along the coincident line from the nozzle to the opposite side (it decreases and then increases again - the claims do not require it to remain decreased nor do the claims preclude a subsequent increase).

With respect to  $\frac{1}{4}$  or more of the cross-sectional area of the bundle, it is asserted that this limitation is met inherently. Further, no cross-sectional area has been specifically defined by Applicant. Thus, a side cross sectional area may be considered based upon a longitudinal slice.

While Boivin et al. does not explicitly set forth a PB/PA ratio of 0.5-0.95, Boivin et al. does disclose decreasing hydraulic permeability as one goes inwardly from the exterior of the fiber bundle ([0023-0025]). Furthermore, the hydraulic permeability is

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shown as higher in areas of more dense fibers ([0021]). Boivin is also silent as to an overall packing ratio of about 0.6.

Haworth et al. discloses a mass transfer device including a hollow fiber bundle wound on a core for radially outward flow (Abstract) wherein the packing fraction of the hollow fibers increases radially outward (C3/L25-43). Additionally, Haworth et al. discloses using incremental packing (C3/L40-53). Furthermore, Haworth et al. discloses that the range of packing fractions be such that the inner fraction is 60-95% of that of the outer packing fraction (C3/L10-27). A membrane occupying rate set to between 0.3-0.6 (C1/L60-C2/L12 - "where the packing fraction approaches the value of about 60%")

Boivin et al. and Haworth et al. are combinable because they are concerned with the same field of endeavor, namely that of varied packing fraction hollow fiber membranes.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hollow fiber membrane structure of Boivin et al. such that the outer most zone and the next zone in of the fibers has a relationship of packing densities such that the inner fraction is 60-95% of the outer fraction and the overall is about 0.6 as taught by Haworth et al. for the purpose of reducing clogging near the core of the membrane and allowing for higher pressure operations.

Regarding claims 3-5, Boivin et al. further discloses multiple zones having differing packing densities, decreasing radially inwardly (see figures 6a-b). Boivin et al. further establishes various ratios between the greatest packing density and lowest



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packing density areas ([0020-0025]). Boivin et al. further discloses securing the membranes using adhesive bonding ([0026]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the packing density relationships to include consideration of 3 zones adjacent to each other such that only one is adjacent or neighboring the inlet and then two others non neighboring to the inlet and having a relationship of packing densities of 0.4-0.6 for the neighboring and 0.2-.04 for the non-neighboring as well as having a ratio such that the occupying rate is no more than 2 times the non-neighboring as a function of mere optimization. Furthermore, Boivin et al. establishes that these general relationships exist in ([0020-0025]) including a relationship between the packing density of the inner most and outer most being not more than 5-10. Accordingly, one having ordinary skill in the art would have known to optimize various ratios of the relationship between zones of the hollow fiber membranes by routine experimentation to achieve desired results as it has been established that the general claim conditions are present. Furthermore, Applicant has not established a criticality of the claimed ratios with regards to specific numerical values. Additionally, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Further note that B1 and B2 may also be interpreted as further concentric rings.

**10. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boivin et al. (US 2002/0079260) in view of Haworth et al. (USP Re. 36,125), and further in view of Misao (JP 62204804) as cited on the IDS.**

Regarding claims 6 and 7, modified Boivin et al. discloses all of the claim limitations as set forth above. Boivin et al. is silent as to the use of a cylindrical current plate accommodating the hollow fiber membrane with a plurality of through holes without one at the nozzle.

Misao discloses in figures 1 and 2 a cylindrical current plate for a hollow fiber membrane with through holes (7) and a wall (8) at the inlet to prevent direct transfer of fluid (see English language abstract).

Boivin et al. and Misao are combinable because they are concerned with the same field of endeavor, namely that of hollow fiber membranes.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the hollow fiber membrane of Boivin et al. to include a current plate such as the one disclosed by Misao for the purpose of preventing damage to the hollow fiber membrane by diverting the flow to avoid direct higher pressure impact to the yarns.

**11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boivin et al. (US 2002/0079260) in view of Haworth et al. (USP Re. 36,125), and further in view of Walker (USP 5,282,966).**

Regarding claim 8, modified Boivin et al. discloses all of the claim limitations as set forth above. While Boivin et al. discloses adhesive bonding the membranes ([0026]), Boivin et al. does not disclose explicitly using a material of high-polymer having a hardness of 50A-70D in a range of operating temperatures.

Walker discloses a membrane separation device (Abstract) which uses standard suitable potting materials (C10/L1-10) comprising of urethane resins and silicone resins

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(C10/L15-25) which inherently would have a shore hardness test of 50A-70D in a range of operating temperatures.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the membrane separator of Boivin et al. to use silicone or urethane potting resins as taught by Walker for the purpose of utilizing well known standard materials to provide a resilient, resistant to breaking potting seal. Furthermore, one having ordinary skill in the art would have chosen urethane or silicone resins over other polymer resins for the purpose of reducing costs and increasing chemical compatibility.

### ***Response to Arguments***

12. Applicant's arguments filed 11/5/2010 have been fully considered but they are not persuasive.

With respect to the membrane occupying rate/packing fraction of Haworth; Haworth explicitly discloses at C1/L62-65 "where the packing fraction approaches 60%". Accordingly, one of ordinary skill in the art would have recognized that Haworth discloses up to 60%. The fact that Haworth discloses an alternative of greater than 60% does not negate the fact that Haworth provides for 60% or approaching.

Applicant alleges Haworth does not disclose an external pressure type hollow fiber module and that external pressure type must be given patentable weight.

This is not persuasive. The instant claims are drawn towards an apparatus. It is well established in the relevant arts that external versus internal pressure is related to the manner of operation. Applicant has provided no explanation or evidence that the limitations of external pressure type limits the physical structure of the instant device. A

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preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). If Applicant is convinced that external pressure imparts physical structure, then Applicant should clarify on the record with evidence or convincing argument and point to the specific structure imparted by this recitation. Furthermore, the device of Haworth would be capable of operation under both internal and external pressure uses. Applicant's arguments towards structure imparted by this limitation thus far have only pointed to examples of manner of operation of membrane devices but no explicit structural feature has been identified by the Applicant that this claim limitation is meant to impart.

With respect to "rod-shaped", Applicant has no explicit definition thereof of this term. "rod-shaped" does not preclude a hollow cored rod.

With respect to  $\frac{1}{4}$  or more of the cross-sectional area of the bundle in Haworth, it is asserted that this limitation is met inherently. Further, no cross-sectional area has been specifically defined by Applicant. Thus, a side cross sectional area may be considered based upon a longitudinal slice.

With respect to Boivin and annular region versus neighboring region, it is noted that Applicant has not claimed any specific shape to neighboring region. Accordingly,

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the limitation is interpreted in its broadest reasonable interpretation. This limitation is capable and in fact reads upon annular shapes.

13. In response to applicant's argument that Boivin and Haworth is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the two references are related to membrane packing in hollow fiber units for blood treatment.

Applicant alleges Haworth's varied packing ratio would destroy the concentric ratio of Boivin.

This is not convincing. The ratio of Haworth "increase radially outward in a major portion of the bundle". Accordingly, Boivin does not preclude minor variations in packing density.

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/  
Primary Examiner, Art Unit 1774

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Examiner, Art Unit 1777